

Message Text

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62

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 ISO-00 OES-05 /034 R

09

DRAFTED BY:DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY:OES/SCI/BMP; MBEAUBIEN

DHEW/OIH/MACODDING

EUR/CE:DANDERSON (INFO)

EUR/CE:BFLATIN(INFO)

EUR/NE:CFLOYD(INFO)

ARA/NC:TWSONANDRES(INFO)

----- 029774

R 241525Z APR 75

FM SECSTATE WASHDC

TO AMEMBASSY BONN

AMEMBASSY BERN

AMEMBASSY CARACAS

AMEMBASSY LONDON

UNCLAS STATE 094429

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, GW, SZ, VE, UK.

SUBJECT: FDA ADVISORY-DEFECTIVE SURGICAL INSTRUMENT

1. FDA ADVISES THAT THE ACMI POLYP RETRIEVER, ALSO REFERRED TO AS POLYGRASPER, A 4 PRONG GRASPING SURGICAL INSTRUMENT MANUFACTURED BY THE AMERICAN CYSTOSCOPE MAKERS, INC, 8 PELHAM PKWY., PELHAM MANOR, N.Y. 10803 - CATALOGUE NO. 9112, DISTRIBUTED BETWEEN SEPTEMBER 28, 1973 AND JANUARY 17, 1974 MAY BE DEFECTIVE. THE PURPOSE OF THIS INSTRUMENT IS TO RETRIEVE AN EXCISED POLYP FROM THE COLON AND TO ALLOW SIMULTANEOUS WITHDRAWAL OF THE POLYP WITH A COLOSCOPE UNDER DIRECT VISUAL CONTROL OF A PHYSICIAN. THE DEFECT NOTED IS THAT THE SOLDER JOINT AT THE DISTAL END BETWEEN THE FLEXIBLE END SECTIONS COMES APART AND PERMITS THE 4 PRONGED GRASPER TO FALL IN THE PATIENT'S COLON.

2. ACCORDING TO THE FIRM, NONE OF THE RECALLED UNITS REMAINS ON THE MARKET. POSTS ARE REQUESTED TO CHECK FOREIGN CONSIGNEES

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TO DETERMINE IF POSSIBLE DEFECTIVE UNITS HAVE BEEN REPLACED.

3. FOREIGN CONSIGNEES AS FOLLOWS:

(1) WAPPLER INTERNATIONAL, TAUNUSSTRASSE 38, 8 MUCHEN 13, WEST GERMANY

(2) DANIELI, A.G., 8123 EBMATINGER, GEWERBEYENTRUM, SCHWEIZ, SWITZERLAND

(3) DR. ENRIQUE MOLINA, CLINICA FALCON, CALLE (EDO ZULLIA) 85-08, MARACAIBO, VENEZUELA.

(4) WAPPLER ENDOSCOPY LTD. 22 PARK AVE., CROYDON, SURREY OYH, UNITED KINGDOM.
KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL CARE, EQUIPMENT, RECALL
Control Number: n/a
Copy: SINGLE
Draft Date: 24 APR 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE094429
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA/JRWEINROTH, M.D.
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750145-0153
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750420/aaaaasiu.tel
Line Count: 76
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: ShawDG
Review Comment: n/a
Review Content Flags:
Review Date: 08 JUL 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <08 JUL 2003 by SilvaL0>; APPROVED <03 FEB 2004 by ShawDG>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
05 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY-DEFECTIVE SURGICAL INSTRUMENT
TAGS: OGEN, ETRD, TBIO, GE, SZ, VE, UK, AMERICAN CYSTOSCOPE MAKERS INC
To: BONN MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006